



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/774,739 02/09/2004 Dean A. Schaefer 1001.1386102 9215

28075 7590 09/15/2009
CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
----------	--------------

3763

MAIL DATE	DELIVERY MODE
-----------	---------------

09/15/2009 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No. 10/774,739	Applicant(s) SCHAEFER ET AL.	
Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 August 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-20, 22-33, 35 and 36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20, 22--33, 35-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Amendment filed on 08/10/09 has been entered.

Claims 16-21, 22-33, 35-36 are present for examination.

Claims 1-15, 21 and 34 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-20, 22, 24, 29-33, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable by Webster, Jr. (US 5,057,092) in view of Kaye (US 4,191,219).

Regarding claim 16, 33, 35-36, Webster discloses a catheter comprising: an elongate shaft 12 including an inner polymer layer 22 defining a lumen of the elongate shaft; a reinforcement layer (including 24, 26, 28) disposed about the inner polymer layer, and an outer polymer layer 30 disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member 24 interwoven with a second helical member 26, and a plurality of axial members 28 disposed between the first helical member and the second helical member in some of plurality of crossover points but not each of the plurality of crossover points as in claim 16.

As known that, one skill in the art would recognize that Webster discloses the reinforcement layer is in the interwoven design structure.

In this case, a fabric woven design is analogous in structure to reinforcement layer of claimed invention. Therefore, the fabric woven design and the reinforcement layer design with interwoven structure are interchangeable and could be used for medical field.

Kaye discloses the fabric interwoven cross construction comprises a first and a second member 16, 18 forming a plurality of crossover point, and a plurality of axial members disposed between the first

Art Unit: 3763

and second member at each of the plurality of crossover point. By positioning the axial member 28 between the helical members 26, no protrusions are formed thereby.

Applicant also admitted that the arrangement of axial member between the helical members, no protrusions are formed thereby maintaining low friction and adequate sealing, pg 13, lines 3-5 of Specification.

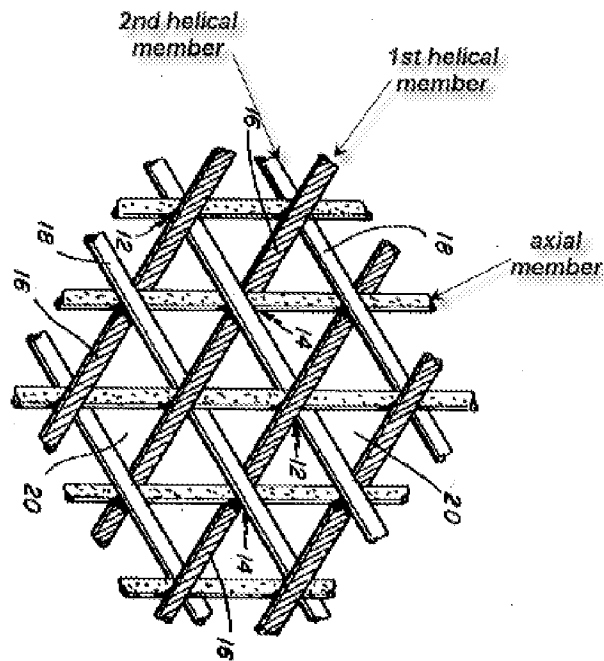
It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with a interwoven cross construction, as taught by Kay, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility.

However, Webster further discloses that the workers skill in the art and technology to which this invention pertains will appreciate the alterations and changes in described apparatus can be practiced without meaning fully departing from the principals spirits and scope of the his invention (col. 4, lines 17-22).

It would have been an obvious matter of design choice to provide the axial member with different arrangement such as disposed between the first and second helical member at each of the plurality of cross over point. Therefore, it appears that the invention would perform equally well with device of Webster.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. "for the entire length of the axial member", a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Art Unit: 3763



Regarding claim 17, the axial members are uniformly spaced about the circumference to the shaft.

Regarding claims 18-19, Webster in view of Kaye discloses the claimed invention (see rejection above). Webster in view of Kaye does not clearly show that four axial members are uniformly spaced apart by 90° about the circumference of the shaft; eight axial members are uniformly spaced apart by 45° about the circumference of the shaft. It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members spaced apart by 45° or 90° solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claim 20, Webster discloses, in Fig. 1, the elongate shaft includes a proximal portion and a distal portion, and wherein the distal shaft portion has fewer axial members 28 than the proximal shaft portion.

Furthermore, it is noted that those skilled in the art will recognize that if an inner diameter of the proximal shaft is larger than an inner diameter of distal shaft portion will give the same result that the distal shaft portion has fewer axial members than the proximal shaft portion.

Art Unit: 3763

For example, Head (US 6,148,865) is one of evidence shows that the distal shaft portion has fewer the axial members 22 the proximal shaft (see Fig. 3A); or Osborne (US 5,251,640) shows that the distal shaft portion has fewer the axial members 12 the proximal shaft (Figs. 1-5).

Not only that, the cross section area or diameter of distal portion of catheter is smaller than proximal portion is very well-known in the catheter art for easy to manipulate or insert into the body.

It would have been an obvious matter of design choice to provide the axial members as listed above, since applicant has not disclosed that the number of axial members solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device of Webster.

Regarding claims 22 and 24, the first and second helical members each comprise polymer material (col. 2, lines 54-65).

Regarding claim(s) 29-32, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

Claims 16-20, 22, 24, 29-33, 35-36 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 5,057,092) in view Huppert (US 2,114,274).

Regarding claims 16-17, 33-36, Webster discloses a catheter comprising: an elongate shaft 12 including an inner polymer layer 22 defining a lumen of the elongate shaft; a reinforcement layer (including 24, 26, 28) disposed about the inner polymer layer, and an outer polymer layer 30 disposed about the reinforcement layer, the reinforcement layer comprising a tubular braid having a first helical member 24 interwoven with a second helical member 26, and a plurality of axial members 28 disposed between the first helical member and the second helical member in some of plurality of crossover points but not each of the plurality of crossover points as in claim 16.

As known that, one skill in the art would recognize that Webster discloses the reinforcement layer is in the interwoven design structure.

Art Unit: 3763

Huppert discloses the tubular braid for use among other purpose. In this case, a medical article such as a catheter tube is analogous in structure to tubular braid of Huppert. Therefore, the braid tubular and the catheter tube are interchangeable and can be used in catheter arts as it relates with the tubular.

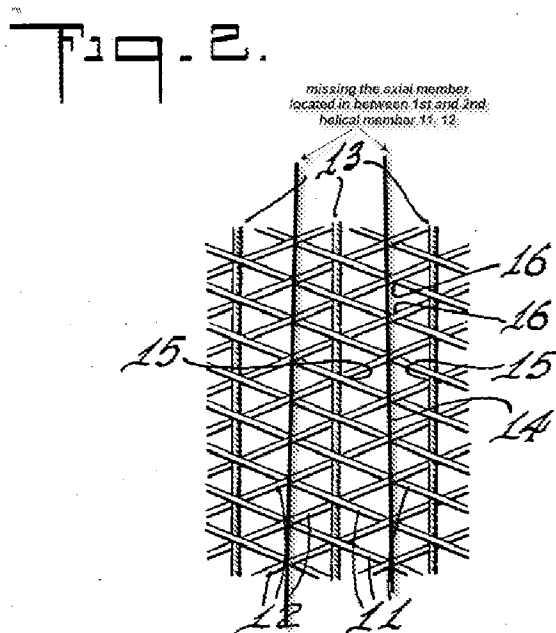
Huppert discloses that device comprising an elongated shaft having a reinforcement/braid layer comprising a tubular braid having a first and second helical member 11, 12 and plurality of axial members 13 disposed between the first and second helical member at some of the plurality of crossover points but not at each of the plurality of crossover points as in claim 16. In other words, there is missing of some of axial members located in between the first and second members as shown in Fig. 2 below.

It would have been an obvious to one of ordinary skill in the art at the time the invention was made to add more axial member for the purpose of increasing the reinforcing or torsional rigidity.

Applicant also admitted that the arrangement of axial member between the helical members, no protrusions are formed thereby maintaining low friction and adequate sealing, pg 13, lines 3-5 of Specification.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster with a interwoven cross construction, as taught by Huppert, in order to prevent slippage, maximize tear resistance, high torsional stiffness, high resiliency and high flexibility.

Art Unit: 3763



Regarding claims 18-20, similarly to the rejection of claims 18-20 under Webster in view of Kaye above.

Regarding claims 22, 24, Huppert discloses the claimed invention except for the first second members and axial members formed of polymeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the helical and axial members formed of polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim(s) 29-32, they encompass the same scope of the invention as to that of claims 16-19 above except they are drafted in method format instead of apparatus format. The claim(s) is/are therefore rejected for the same reason as set forth above.

Claims 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 5,057,092) in view of Kaye or Huppert and further in view of Mortier et al. (US 5,730,733).

Art Unit: 3763

Webster in view of Kaye or Huppert discloses the claimed invention (see rejection above).

Webster in view of Kaye does not disclose that the first and second helical members each comprise a plurality of monofilaments; wherein the monofilaments comprise LCP; the monofilaments are arranged side-by-side to collectively define a flat ribbon.

Mortier discloses that a first and second helical members 32 or 34 (Fig. 2A) each comprises a plurality of monofilaments 26, 36; wherein the monofilaments comprise LCP (liquid crystal polymer material), (col. 4, lines 18-30); the monofilaments are arranged side-by-side to collectively define a flat ribbon.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Webster in view of Kaye/Huppert with a plurality of monofilaments, as taught by Mortier, in order of increase the torsional rigidity and more flexible.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent Nos. 6,709,429.

Art Unit: 3763

Claims 16, 22-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-9, 11, 13-28 of U.S. Patent Nos. 6,942,654.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device and method of instant claims are fully disclosed and covered by the claims in the U.S. patents. 6,709,429 and 6,942,654.

Response to Arguments

Applicant's arguments filed 08/10/09 have been fully considered but they are not persuasive..

1. Applicant argues that nowhere Webster or Kaye discloses that the lumen of the elongated shaft and an outer surface of the outer polymer layer are free from radial protrusion.

In response, Webster does not mention that the lumen of the elongated shaft and an outer surface of the outer polymer layer are free from radial protrusion. However, the interwoven arrangement of Kaye by positioning the axial members between the first and second member 16, 18 will bring the result that no protrusions are formed thereby. This interwoven arrangement of Kaye is exactly same as current applicant. Applicant also admitted that with this interwoven arrangement causes no protrusions are formed, page 13, lines 3-5.

Therefore, one skill in the art would recognize that the device of Webster in view of Kaye will bring the result such as the lumen of the elongated shaft and an outer surface of the outer polymer layer are free from radial protrusion.

2. In response to applicant's argument that fabric for a needlepoint canvas formed of yarn as taught by Kaye is clearly nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the interwoven arrangement of Kaye to improve the flexibility and maximize tear resistance. Therefore, one skill in the art would recognize that the interwoven arrangement of Kaye should be applied in Webster's device to improve the flexibility, elasticity and maximize tear resistance.

Art Unit: 3763

3. Applicant argues that Huppert does not disclose an inner polymer layer defining a lumen of the elongate shaft, reinforcement disposed about the inner polymer layer, and an outer polymer disposed about the reinforcement layer, as recited in claims 16, 29 and 33.

In response, please see new ground rejection of Webster in view of Huppert above for more details.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763